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Midwife managed delivery unit: a randomised controlled comparison with consultant led care

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Abstract

***Objective*—To examine whether intrapartum care and delivery of low risk women in a midwife managed delivery unit differs from that in a consultant led labour ward.**

***Design*—Pragmatic randomised controlled trial. Subjects were randomised in a 2:1 ratio between the midwives unit and the labour ward.**

***Setting*—Aberdeen Maternity Hospital, Grampian.**

***Subjects*—2844 low risk women, as defined by existing booking criteria for general practitioner units in Grampian. 1900 women were randomised to the midwives unit and 944 to the labour ward.**

***Main outcome measures*—Maternal and perinatal morbidity.**

***Results*—Of the women randomised to the midwives unit, 647 (34%) were transferred to the labour ward antepartum, 303 (16%) were transferred intrapartum, and 80 (4%) were lost to follow up. 870 women (46%) were delivered in the midwives unit. Primigravid women (255/596, 43%) were significantly more likely to be transferred intrapartum than multigravid women (48/577, 8%). Significant differences between the midwives unit and labour ward were found in monitoring, fetal distress, analgesia, mobility, and use of episiotomy. There were no significant differences in mode of delivery or fetal outcome.**

***Conclusions*—Midwife managed intrapartum care for low risk women results in more mobility and less intervention with no increase in neonatal morbidity. However, the high rate of transfer shows that antenatal criteria are unable to determine who will remain at low risk throughout pregnancy and labour.**

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Introduction

If women are to have choice in the location for their delivery, the maternity services must provide a safe and acceptable range of options. In Aberdeen we have developed a midwife managed delivery unit that aims to offer women choice, participation, and control in their labour. Over the past 40 years in Britain women have had less choice as the proportion of babies delivered in consultant maternity units has increased and maternity services have moved away from community based delivery. It has been argued that hospital delivery provides greater safety for mother and baby[1-3] but some researchers disagree.[4]

This debate on the place of delivery and its safety is not new, but it has intensified in the past two years with the publication of recent reports and policy documents.[5-7] Most would agree that close supervision and monitoring of high risk pregnancies is beneficial. However, the application of the same criteria to low risk pregnancies has been questioned. There is some evidence to suggest that there is more intervention in labour and greater maternal morbidity if a low risk woman is cared for in a consultant maternity unit rather than in a general practitioner unit[8-14] or by midwives in a birth room.[15-17] Yet in many of these studies the sample populations have been small or not directly comparable. In all but three of the studies[15-17] selection bias may have been introduced due to preference for a particular type of care. The experience of the family birthing unit in Melbourne showed that intrapartum problems do occur in low risk women,[15] thus highlighting the importance of the close proximity of specialist obstetric, anaesthetic, and neonatal services. Further evaluation of alternative methods of obstetric care, in particular midwife managed care, is required. In this paper we report the results of one such evaluation of a midwifery managed delivery unit in the Aberdeen Maternity Hospital.

Methods

BACKGROUND

The midwives unit in Aberdeen was established in April 1990. It is a separate unit, of five single rooms, located 20 yards from the consultant led labour ward. The philosophy of care behind the unit is to provide a safe, "homely" environment where women can retain choice and control in the management of their labour. Midwives take total responsibility for the care delivered, thus developing and maintaining their competence. Labour is managed traditionally—the fetal heart rate is monitored with a Pinard stethoscope or hand held Doppler apparatus, active labour is encouraged, and there is minimal intervention. The unit is staffed and run by hospital midwives who work throughout the delivery suite according to clinical need. There is no input to the midwives unit by medical staff. However, the unit caters solely for low risk women and there are strict protocols for booking, admission, and transfer.

STUDY AIMS

The main objective was to compare care and delivery of low risk women in a midwife managed delivery unit with care and delivery in the consultant led labour ward in terms of four sorts of outcomes. As well as maternal and perinatal morbidity, reported here, we looked at the expectations, experiences, and satisfaction of parturient women; the role, experiences, and satisfaction of midwifery staff, and costs of care. These other outcomes will be reported elsewhere.

STUDY POPULATION

Low risk women were identified from general practitioners' referral letters. The exclusion criteria for the

study were those established for booking women for delivery in general practitioner units in Grampian. These were pre-existing maternal disease, infertility, a complicated obstetric history (for example, previous caesarean section, difficult vaginal delivery, or poor obstetric outcome), height < 150 cm, maternal age > 35 years, or multiple pregnancy.

Of 3451 women identified as eligible for the study, 2844 women agreed to participate. This exceeded our target sample size of 2700 women designed to yield 80% power of detecting, at the 5% significance level, a difference of 5% in perinatal morbidity—for example, from 25% to 30%.[18] Morbidity was chosen as the principal measure of outcome rather than mortality because intrapartum perinatal mortality is less than 1/1000. To show a difference in perinatal mortality would have required a much larger sample size.

All low risk women booking between October 1991 and December 1992 were invited to participate in the study through an explanatory letter. Further information was given at the booking visit by a midwife, and women's consent was obtained. All women had delivered by August 1993.

TRIAL DESIGN

This was a pragmatic randomised controlled trial. That is, in setting up the trial the researchers recognised that because behaviour is dictated by practical consequences women may deviate from the protocol of the study. This was allowed for in the analysis and is discussed later. At booking, women identified as low risk were randomised to deliver in either the midwives unit or the consultant led labour ward by opening consecutive sealed opaque envelopes which contained the place for delivery. The randomisation was done in a simple, unstratified manner. An initial allocation of 2:1 in favour of the midwives unit was used because of the expected transfer of women with complications from the midwives unit to the labour ward. This ratio was necessary to ensure that the space in the midwives unit was fully utilised. The antenatal care of all women participating in the study was otherwise identical to that received by other women booking at the hospital.

DATA COLLECTED

Information in this report was collected from six sources:

Staff questionnaire, completed by the midwife in charge of the delivery as soon after the birth as possible; client questionnaire, completed by the woman after discharge home; interviews of a random sample of 400 women drawn from the study population; case note review; SMR2 (Scottish Morbidity Register) forms; Aberdeen maternity and neonatal databank. Data validation was carried out by cross checking key variables across the different study records held for each woman in the database manually with case records and by estimation of keying errors for a subsample of questionnaires.

ANALYSIS AND STATISTICAL METHODS

Data were analysed by using the statistical package SPSS.[19] The strategy of analysis was by intention to treat—that is, all subjects were analysed in the group to which they were initially allocated, whether or not they completed, or indeed received, that care. This pragmatic method of analysis permits unbiased estimates of the performance of the midwives unit under normal clinical conditions, which would allow transfer to the labour ward both before and during labour. This strategy of analysis avoids misinterpretation of the data which can occur when subjects are withdrawn because of protocol deviations.[20]

Categorical variations were analysed by using the χ^2 test and continuous variables with a normal distribution by the Student's t test. Length of labour (first stage), estimated blood loss, and length of stay in the neonatal unit required a log transformation to normality, hence geometric means are reported for these variables. Data with a non-normal distribution were analysed by using the Mann-Whitney U test. Significance levels are quoted in the tables with appropriate 95% confidence intervals for the difference in proportions in the text.

Results

Baseline characteristics are shown in table I. There seemed to be little difference between the groups.

Nineteen hundred women (67%) were randomised to the midwives' unit and 944 (33%) to the labour ward. Of the women randomised to the unit, 727 (38%) were transferred antepartum and 303 (16%) were transferred intrapartum. In total, 870 women (46%) were delivered in the midwives unit. The antepartum transfer group included 80 women, 4% of the population booked for the midwives unit, for whom follow up was not possible (35 miscarried, 11 underwent termination of pregnancy, and 34 moved outside the Grampian area).

Induction of labour for postmaturity (155/1900, 8%) was the most common reason for antepartum transfer (table II). This, with pregnancy induced hypertension and prolonged rupture of membranes, accounted for 44% of antepartum transfers (317/727). Twenty six per cent of all women who entered the midwives unit in labour (303/1173) were transferred (table III).

Primigravid women (255/596, 43%) were significantly more likely to be transferred intrapartum than

TABLE I—*Characteristics of women randomised to midwives unit or labour ward. Values are numbers (percentages) unless stated otherwise*

	Midwives unit	Labour ward
Mean (SD) age at delivery (years)	28 (4·4) n=1675	28 (4·5) n=789
Mean (SD) maternal height (cm)	163 (5·8) n=1674	163 (5·9) n=793
Parity:		
Primiparous	929 (56)	451 (57)
Multiparous	745 (44)	338 (43)
Social class:		
I	190 (12·0)	97 (12·2)
II	317 (20·0)	141 (17·8)
III Non-manual	165 (10·4)	91 (11·5)
III Manual	453 (28·6)	44 (30·8)
IV	377 (23·8)	173 (21·8)
V	80 (5·1)	47 (5·9)
Mean (SD) age on leaving full time education:		
Woman	17·5 (2·5) n=1640	17·4 (2·4) n=772
Partner or husband	17·7 (2·9) n=1552	17·5 (3·0) n=737

TABLE II—*Reason for antepartum transfer from the midwives unit*

	No (%) of women
Induction of labour for postmaturity	155 (21·3)
Pregnancy induced hypertension	93 (12·8)
Prolonged rupture of membranes	69 (9·5)
Antepartum haemorrhage	55 (7·6)
Malpresentation	55 (7·6)
Preterm labour	49 (6·7)
Reduced fetal movement or poor cardiotocograph	37 (5·1)
Intrauterine growth retardation	20 (2·8)
Gestational diabetes or polyhydramnios	17 (2·3)
Delivered in peripheral hospital	14 (1·9)
Home delivery	2 (0·3)
Intrauterine death	5 (0·7)
Fetal abnormality	3 (0·4)
Born before arrival	11 (1·5)
Maternal request	9 (1·2)
Other:	
Clinical*	53 (7·2)
Follow up not possible	80 (11·1)
Total	727 (100)

*Including staff errors (7), induction of labour for social reasons (5), and twins (4).

TABLE III—*Reason for intrapartum transfer from the midwives unit (n=303). Values are numbers (percentages)*

	Primigravida women (n=255)	Multigravida women (n=48)	Total (n=303)
Fetal distress	99 (39)	22 (46)	121 (40)
Meconium	58 (23)	16 (33)	74 (24)
Fetal heart rate	41 (16)	6 (13)	47 (16)
Delay in labour	96 (38)	12 (25)	108 (36)
First stage	64 (25)	11 (23)	75 (25)
Second stage	32 (13)	1 (2)	33 (11)
Pregnancy induced hypertension	25 (10)	3 (6)	28 (9)
Epidural anaesthesia	24 (9)	4 (8)	28 (9)
Other	11 (4)	7 (15)	18 (6)

TABLE IV—*Events during labour. Values are numbers (percentages) unless stated otherwise*

Variable	Midwives unit (n=1819)	Labour ward (n=915)	P value
Onset of labour:			
Spontaneous	1414 (78·6)	727 (80·1)	0·4
Induced	385 (21·4)	181 (19·9)	
Augmented labour	274 (15·3)	135 (14·9)	0·9
Mean (SD) gestation (weeks)	39·7 (1·8)	39·8 (1·6)	0·9
Mean (SD) length of labour (hours)	9·6 (6·1)	9·2 (6·0)	0·2
First stage*	7·0 (6·8 to 7·2)	6·8 (6·4 to 7·1)	0·3
Second stage	0·9 (1·0)	0·9 (1·0)	0·7
Delay in labour:			
First stage	57 (3·1)	20 (2·2)	0·2
Second stage	94 (5·2)	47 (5·1)	1·0
Monitoring:†			
Pinard	506 (30·2)	119 (15·1)	0·001
Doppler	917 (54·8)	81 (10·3)	0·001
Cardiotocograph	959 (57·3)	732 (92·8)	0·001
Fetal scalp electrode	461 (26·1)	285 (31·9)	0·001
Analgesia:			
None	32 (1·9)	14 (1·8)	0·9
Natural methods	901 (53·8)	355 (45·0)	0·001
Entonox	1408 (84·1)	657 (83·3)	0·6
TENS	578 (34·5)	216 (27·4)	0·001
Pethidine or diamorphine	1063 (63·5)	498 (63·1)	0·9
Epidural or spinal anaesthesia	246 (14·7)	140 (17·7)	0·05
Mobility:			
Able to move most of time	1030 (63·5)	388 (51·6)	0·001
Unable to move	592 (36·5)	364 (48·4)	
Complications:			
Fetal distress	336 (18·5)	205 (22·4)	0·02
Meconium stained liquor	251 (13·8)	129 (14·1)	0·9
Pre-eclampsia	51 (2·8)	17 (1·9)	0·2
Preterm delivery (<37 weeks)	48 (2·6)	27 (3·0)	0·6
Shoulder dystocia	26 (1·4)	8 (0·9)	0·3
Undiagnosed malpresentation	13 (0·7)	4 (0·4)	0·5
Other	40 (2·2)	30 (3·3)	0·1

*Geometric mean (95% confidence interval).
†Monitoring: method (95% confidence interval for difference): intermittent—by Pinard stethoscope (12% to 19%); intermittent—by Doppler (41% to 48%); continuous—by cardiotocograph (−39% to −32%).

multigravid women (48/577, 8%) (95% confidence interval for difference in proportions, 30% to 39%). Suspected fetal distress was the most common reason for intrapartum transfer—40% of all intrapartum transfers were for this reason (121/1173, 10%). The proportion of women transferred for delay in first stage labour was similar for both primigravid (25%; 64) and multigravid (23%; 11) women. However, primigravid women were significantly more likely to be transferred in second stage (13%; 32) than multigravid women (2%; 1) (95% confidence interval for difference in proportions, 5% to 16%).

Significant differences were found in monitoring, fetal distress, analgesia, and mobility (table IV). Women allocated to the midwives unit were significantly less likely to have continuous electronic fetal heart rate monitoring and more likely to have intermittent monitoring by Pinard stethoscope or hand held Doppler (P=0·001). The increased electronic monitoring in the labour ward group might explain the more frequent observation of fetal distress (difference in proportions=3·9%; 95% confidence interval 1% to 7%). This in turn may be the reason for the significantly higher use of fetal scalp electrodes in the labour ward group (difference in proportions=5·8%; 2% to 10%).

Significantly more women allocated to the midwives unit reported using natural methods of pain relief (difference in proportions=8·8%; 5% to 13%). These methods included breathing, massage, moving around, and having a bath. They were also more likely to have tried transcutaneous electrical nerve stimulation (TENS) (difference in proportions=7·1%; 3% to 11%). Women allocated to the labour ward, on the other hand, were more likely to have had an epidural anaesthetic for pain relief.

Women allocated to the midwives unit were significantly more likely to be able to move around for most of the time during labour (difference in proportions=11·9%; 8% to 16%). Restricted mobility was most commonly due to the woman being attached to a monitor or drip or having had an epidural.

There was no difference in the number of women having a normal delivery (difference in proportions=2·9%; −0·5% to 6%). The only outcome of labour that was statistically different was a lower episiotomy rate among women allocated to the midwives unit (difference in proportions=3·9%; 0·1% to 8%, table V).

There were more neonatal deaths in the midwives unit group and a higher percentage of stillbirths in the labour ward group, but because of the comparatively small numbers these differences do not reach statistical significance. In all 10 cases of stillbirth the fetal heartbeat was absent on admission to hospital. There was one stillbirth due to fetal abnormality in each group. In the midwives unit group, one stillbirth occurred as a direct result of maternal death due to an aortic aneurysm. Five of the neonatal deaths resulted from lethal fetal abnormalities, such as Potter's syndrome. Of the other six neonates who died, four were of less than 37 weeks' gestation. The remaining two deaths occurred in the midwives unit group. One neonatal death is suspected to have been caused by intrapartum asphyxia after induction of labour. This woman was therefore transferred antenatally and never entered the midwives unit. In the second case, the woman started her care in the midwives unit. When spontaneous rupture of membranes revealed thick meconium, she was immediately transferred to the labour ward for continuous monitoring and was delivered by emergency caesarean section 18 hours later.

Apgar scores at 1 and 5 minutes and cord pH were identical in both groups. Babies born to women in the midwives unit group were more likely to receive resuscitation. This was accounted for by an increased administration of naloxone. The number of babies admitted to the neonatal unit was similar in both groups.

Discussion

This study identified differences in the intrapartum care of low risk women in a midwife managed delivery unit and a consultant led labour ward. The one other randomised study that has compared these alternatives differs from this study in that both antenatal and intrapartum care were managed by midwives.[17] Our results are remarkably similar in terms of monitoring, detection of fetal distress, and rate of episiotomy. However, this study did not detect the differences in the incidence of delay in labour which were found by MacVicar *et al.*[17]

The introduction of one intervention, continuous fetal heart rate monitoring, seems to have led to a cascade of further intervention. It was decided, for the purposes of this study, to maintain the existing policy of active encouragement of electronic monitoring of women allocated to the labour ward. This provided an opportunity to study the effects of this policy on morbidity. Previous studies have shown continuous fetal heart rate monitoring to be associated with an increase in reported occurrences of fetal distress[21] and caesarean section.[22] The increased use of fetal scalp

electrodes and reported occurrence of fetal distress in the labour ward group would seem to confirm this. However, in common with previous studies, the difference in mode of delivery in this study was not large enough to reach statistical significance and it may be that meta-analysis could be useful here. Despite the difference in fetal distress, perinatal outcomes were similar in both groups.

It has also been suggested that restriction in mobility, which in this study occurred as a result of an increase in continuous fetal heart rate monitoring and epidural anaesthesia, may increase the incidence of fetal heart rate abnormalities.[23] Furthermore, upright posture or ambulation has been associated with a reduced use of narcotic analgesia or epidural anaesthesia.[24] This would account for the borderline difference in epidural use between the two groups.

There was a marginally higher incidence of episiotomy among the women allocated to the labour ward. This may be explained in part by the higher incidence of assisted vaginal delivery.

The slightly higher incidence of neonatal resuscitation among babies of women allocated to the midwives unit was accounted for by a higher rate of administration of nalaxone. Despite this there were no differences in perinatal outcomes.

Criteria for identifying women as low risk are based traditionally on the proposals of the Cranbrook committee in 1959,[25] although the validity of using these criteria has been questioned.[26] Despite careful selection of low risk women the study found a high incidence of transfer. These results emphasise the unpredictability of screening women on the basis of these criteria, particularly if this is done at the beginning of pregnancy. The high intrapartum transfer rate of primigravid women raises doubts about the suitability of booking them, on the basis of these criteria, for delivery in peripheral maternity units and has implications for service development.

TABLE V—*Outcomes of labour. Values are numbers (percentages) unless indicated otherwise*

Variable	Midwives unit (n=1819)	Labour ward (n=915)	P value
Mode of delivery:			
Spontaneous vaginal delivery	1422 (78·2)	689 (75·3)	
Vaginal breech	23 (1·3)	12 (1·3)	
Forceps or ventouse	221 (12·2)	122 (13·3)	0·5
Emergency caesarean section	126 (6·9)	73 (8·0)	
Elective caesarean section	27 (1·5)	19 (2·1)	
State of perineum (excluding caesarean section):			
Intact	394 (23·7)	171 (20·9)	
Episiotomy	420 (25·2)	238 (29·1)	0·8†
Tear	850 (51·1)	410 (50·1)	
Third degree tear	15 (0·8)	3 (0·3)	0·1
Mean (95% confidence interval) estimated blood loss*	156 (151 to 161)	163 (156 to172)	0·1
Placental delivery:			
Controlled cord traction	1692 (94·7)	863 (95·6)	
Maternal effort	55 (3·1)	22 (2·4)	
Manual removal, without anaesthetic	14 (0·8)	4 (0·4)	0·6
Manual removal, under general anaesthetic or epidural	26 (1·5)	14 (1·6)	
Mean (SD) length of stay on postnatal ward (days)	4·3 (2·0)	4·4 (2·0)	0·2

*Geometric mean. †P=0·04 for episiotomy.

TABLE VI—*Comparison of fetal outcomes*

Variable	Midwives unit (n=1900)	Labour ward (n=944)	P value
No (%) of infants:			
Live born	1805 (99·2)	912 (99·3)	
Stillborn	6 (0·3)*	4 (0·4)	0·5
Neonatal death	9 (0·5)	2 (0·2)	
Termination of pregnancy or miscarriage	46 (2·4)	17 (1·8)	0·4
Lost to follow up	34 (1·8)	9 (1·0)	0·1
Mean (SD) weight of infant at birth (g)	3427 (519)	3420 (493)	0·8
Median (interquartile range) Apgar score:			
At 1 minute	9 (8 to 9)	9 (8 to 9)	0·6†
At 5 minutes	9 (9 to 9)	9 (9 to 9)	0·5†
Mean (SD) pH of cord	7·294 (0·096)	7·294 (0·100)	1·0
Resuscitation:			
None or mucus extraction only	1431 (79·4)	750 (82·6)	
Naloxone with or without oxygen or IPPV	269 (14·9)	113 (12·4)	0·1§
Oxygen or IPPV only	103 (5·7)	45 (5·0)	
No (%) of babies admitted to neonatal unit:			
Total	143 (7·9)	67 (7·4)	
For up to 48 hours	24 (1·3)	13 (1·4)	0·8
For more than 48 hours	119 (6·6)	54 (6·0)	
Mean‡ (95% confidence interval) length of stay (days)	3·5 (2·9 to 4·2)	3·3 (2·4 to 4·4)	0·8

IPPV=intermittent positive pressure ventilation.
*Includes one fetal death associated with maternal death.
†Mann-Whitney U test.
‡Geometric mean.
§P=0·05 for no resuscitation or mucus extraction only.

Clinical implications

- Midwife managed intrapartum care results in more mobility and fewer epidural anaesthetics and episiotomies with no increase in neonatal morbidity
- Half of women who are identified as low risk at booking, using existing criteria, will become high risk during pregnancy or labour
- The high rate of intrapartum transfer to consultant led care in primigravid women should be noted by those deciding on criteria for delivery in stand alone units

CONCLUSION

This study confirms that midwife managed care is as safe as the standard consultant led care. Indeed, the lower rate of intervention among women allocated to the midwives unit indicates that this alternative is the more effective option for women at low risk. However, the high rate of transfer shows that antenatal criteria are unable to determine who will remain at low risk throughout pregnancy and labour.

Other issues that should be considered in planning future maternity services include the continuity of care, the satisfaction of the women using the services and the staff delivering the services, and the costs of care.

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Impact of massive dose of vitamin A given to preschool children with acute diarrhoea on subsequent respiratory and diarrhoeal morbidity

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Abstract

***Objective*—To assess the impact of vitamin A supplementation on morbidity from acute respiratory tract infections and diarrhoea.**

***Design*—Double blind randomised placebo controlled field trial.**

***Setting*—An urban slum area in New Delhi, India.**

***Subjects*—900 children aged 12-60 months attending a local health facility for acute diarrhoea of less than seven days' duration randomly allocated to receive vitamin A 200 000 IU or placebo.**

***Main outcome measures*—Incidence and prevalence of acute lower respiratory tract infections and diarrhoea during the 90 days after termination of the enrolment diarrhoeal episode measured by twice weekly household surveillance.**

***Results*—The incidence (relative risk 1·07; 95% confidence interval 0·92 to 1·26) and average number of days spent with acute lower respiratory tract infections were similar in the vitamin A supplementation and placebo groups. Among children aged 23 months or less there was a significant reduction in the incidence of measles (relative risk 0·06; 95% confidence interval 0·01 to 0·48). The incidence of diarrhoea was also similar (relative risk 0·95; 0·86 to 1·05) in the two groups. There was a 36% reduction in the mean daily prevalence of diarrhoea associated with fever in the vitamin A supplemented children older than 23 months.**

***Conclusions*—Results were consistent with a lack of impact on acute lower respiratory tract related mortality after vitamin A supplementation noted in other trials and a possible reduction in the severity of diarrhoea.**

Introduction

Clinical vitamin A deficiency as manifested by mild xerophthalmia predisposes to increased diarrhoea and respiratory morbidity.[1,2] The reported 20-54% reduction in mortality after vitamin A supplementation in preschool children in developing countries, however, seems larger than the maximal possible if the beneficial effect was restricted to the clinically vitamin A deficient population only.[3-5] Some of the observed benefit is postulated to be through correction of subclinical deficiency.[3,5,6] If this is true, then the impact of vitamin A supplementation on morbidity based on the prevalance of xerophthalmia would be an underestimate. There is thus a need to investigate the impact of vitamin A on morbidity directly.

Vitamin A supplementation, if focused on children seeking care for diarrhoea, would reach a substantial proportion of those clinically or subclinically deficient in vitamin A.[5] About two thirds of a large dose of vitamin A given to children with diarrhoea was shown to be absorbed and to cure clinical xerophthalmia.[7-9]

We conducted a trial to see whether 200 000 IU of vitamin A given to children aged 12-60 months with acute diarrhoea would reduce the incidence and severity of diarrhoea and lower respiratory tract infections during the subsequent three months.

Subjects and methods

The study was conducted at Govindpuri, an urban slum area in south Delhi with a population of 30 000. Men were most commonly employed as manual labourers. Few (5%) women worked outside the home. Almost all obtained drinking water from public hand pumps and used communal toilets. Health services were provided primarily by an adjacent government clinic and a few small private clinics. Vitamin A prophylaxis had not routinely been given to the study population in the preceding three years.

Children attending the government clinic were enrolled into the study if they were 12-60 months of age, if the duration of their diarrhoea was seven days or less, if their weight for height was 70% or more of the National Center for Health Statistics median, and if they resided in the slum area. Of the 1258 children with acute diarrhoea attending the clinic, 900 fulfilled the inclusion criteria and were enrolled. Among the remaining 358 children, the first identified reason for exclusion was: presence of signs and symptoms of vitamin A deficiency (30; 8·4%), had received a large dose of vitamin A in the past six months (29; 8·1%), was likely to migrate out of the study area (157; 43·9%), had associated systemic illness (82; 22·9%), had already been enrolled in the study within the preceding six months (28; 7·8%), had weight for height less than 70% of the National Center for Health Statistics median (4; 1·1%), and refused consent (28; 7·8%). Of the 30 excluded children with vitamin A deficiency, 16 had night blindness and 14 Bitot's spots. Among the 1258 eligible children, clinical vitamin A deficiency was seen in 13 (1·0%) at age 23 months or less, 67 (5·3%) at 24-36 months, and 40 (3·2%) beyond 36 months.

Informed consent was obtained and the selected children examined by a physician. Details were sought on the socioeconomic status of the family, characteristics of the enrolment illness, and feeding practices before the illness. The study was approved by the institutional ethics committee.

RANDOMISATION

Children were randomised to receive vitamin A

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